

**REMARKS**

Claims 1-34 were originally filed in the present application. Of the pending claims, Claims 1-34 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which Applicant regards as the invention. The rejection is based on the Examiner's understanding that the claims "are drawn to 'a pair of antibodies specific to' PrP<sup>SC</sup>" while the specification "teaches only one antibody which is utilized two times." The Examiner has characterized the antibody as being "[f]irst...a labeled antibody and second it is nonlabeled."

The Examiner's position and reading of the specification, however, is unsupported by the text of the specification. Applicant respectfully traverses this present rejection under 112 and seeks reconsideration based on the following remarks.

With respect to the language of the claims, Claim 1 and its dependants (Claims 2-13) recite the phrase "using a pair of antibodies specific to the analyte" while Claim 14 and its dependents (Claims 15-24) recite "a pair of antibodies specific for PrP<sup>SC</sup>." Independent Claim 25 and its dependents (Claims 26, 27, and 29-34) contain no such limitation. The remaining dependent claim (Claim 28) recites "a pair of antibodies specific to the PrP<sup>SC</sup>" but characterizes the antibodies as "immobilized on the membrane" and the other "being labeled . . . ."

Accordingly, at least Claims 25-27 and 29-34 should be excepted from the present rejection.

Further, with respect to the specification language, the teaching is quite clear that the present invention utilizes two different antibodies. For example, at page 5, line 9 and line 18, the specification calls for "a pair of antibodies specific to the . . . protein analyte." At page 10, line 8 through page 11, line 7, the specification describes "a pair of antibodies specific to PrP<sup>SC</sup>" which include "a labeled antibody that 'detects' the PrP<sup>SC</sup> and . . . an immobilized antibody that 'captures' the prion protein-antibody-label complex to form a 'sandwich.'" The specification goes on to describe the labeled antibody as binding to "a particular epitope of the PrP<sup>SC</sup> to form a prion protein-antibody-label complex" while the second specific antibody, which is immobilized

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on the test membrane, “binds to the second epitope of the PrP<sup>SC</sup> to which it is specific. . . .” The result is the analyte becomes “‘sandwiched’ between the two antibodies.” As one possible embodiment of the present invention, the specification teaches that the “resulting ‘sandwiched’ PrP<sup>SC</sup> produces a detectable change in the membrane, such as the formation of a colored test line, which indicates a positive result.”

The unique purpose of each antibody is highlighted even further in the discussion on page 19, lines 1-7. The specification here explains that in one embodiment of the invention the homogenized sample, including any PrP<sup>SC</sup>, flows through the test device until it reaches the labeled antibody. The antibody attaches to the antigen, if present, to form a labeled complex. The resulting complex then “migrates through the detection zone membrane toward the immobilized antibody where it complexes” to form a readable response on the membrane.

Finally, referring to page 22, lines 11-17, the specification identifies a first and second antibody and states “each specific for a different epitope of the pathogenic prion . . . .” This is significant because, as is well-known in the art, the epitope and antibody relationship is analogous to that of the lock and key. A key is designed to fit and unlock a single, specifically configured lock such that two different locks require two different keys. Likewise, two different epitopes would require two different antibodies.

Clearly, the Examiner’s contention that the “specification teaches only one antibody which is utilized two times” is incorrect. Reconsideration of the present rejection is requested, and a substantive examination of the pending claims is earnestly sought.

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Attorney Docket No. 3873 P 011

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### CONCLUSION

Claims 1-34 are presently pending in the referenced application. No amendments have been made to the claims or specification. Applicant believes that all pending claims are allowable, and a notice to that effect is earnestly sought at the Examiner's earliest convenience. Reconsideration of all pending claims is hereby requested. If any informalities remain which may be cleared up by Examiner amendment, Applicant requests the Examiner to call the undersigned attorney at his convenience.

The Commissioner is authorized to debit or credit our Deposit Account No. 23-0280 for any payment **deficiencies or overpayments** associated with this matter.

Respectfully submitted,

Date: February 13, 2004

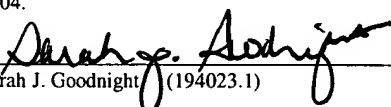
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**CERTIFICATE OF MAILING (37 C.F.R. § 1.8a)**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to: Mail Stop Non-Fee Amendment, Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450, on February 13, 2004.

  
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